

DURABLE MEDICAL EQUIPMENT, ORTHOTICS, OSTOMY SUPPLIES, MEDICAL SUPPLIES AND REPAIRS/REPLACEMENTS

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INSTRUCTIONS FOR USE

This Coverage Determination Guideline provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Coverage Determination Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Coverage Determination Guideline. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Coverage Determination Guideline. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Coverage Determination Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this guideline, please check the member specific benefit plan document and any federal or state mandates, if applicable.

For self-funded plans with SPD language other than fully-insured Generic COC language, please refer to the member specific benefit plan document for coverage.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Indications for Coverage

Durable Medical Equipment (DME) is a Covered Health Care Service when the member has a DME benefit, the equipment is ordered by a physician to treat an injury or sickness (illness) and the equipment is not otherwise excluded in the benefit plan document.

DME must be:

- Ordered or provided by a physician for outpatient use primarily in a home setting;
- Used for medical purposes;
- Not consumable or disposable except as needed for the effective use of covered DME; and
- Not of use to a person in the absences of a disease or disability.

Breast Pumps

Breast pumps may be covered under the preventive care services benefit. Refer to the Coverage Determination Guideline titled [Preventive Care Services](#) for breast pump coverage indications.

Contact Lenses & Scleral Bandages (Shells)

Contact lenses or scleral shells that are used to treat an injury or disease (e.g., corneal abrasion, keratoconus or severe dry eye) are not considered DME and may be covered as a therapeutic service. In these situations, contact lenses and scleral shells are not subject to a plan's contact lens exclusion.

Cranial Remolding Orthosis

Cranial molding helmets (cranial remolding orthosis, billed with S1040) used to facilitate a successful post-surgical outcome are covered as DME and are not subject to the orthotic device exclusion. For all indications, refer to the Medical Policy titled [Plagiocephaly and Craniosynostosis Treatment](#).

Note: A protective helmet (HCPCS code A8000–A8004) is not a cranial remolding device. It is considered a safety device worn to prevent injury to the head rather than a device needed for active treatment; see [Coverage Limitations and Exclusions](#).

Enteral Pumps

Enteral pumps are covered as DME, even when the enteral nutrition formula is not covered. Please check the member specific benefit plan document for coverage of enteral pumps.

Implanted Devices

Any device, appliance, pump, machine, stimulator, or monitor that is fully implanted into the body is not covered as DME. (If covered, the device is covered as part of the surgical service.)

Note:

Cochlear Implant Benefit Clarification: If benefits exist for a cochlear implant, the external components (i.e., speech processor, microphone, and transmitter coil) are considered under the DME benefit, and the implantable components are considered under the medical-surgical benefit. The member specific benefit plan document must be referenced to determine if there are DME benefits for repair or replacement of external components.

Insulin Pumps

Insulin pumps are considered DME. For state specific information on mandated coverage of diabetes supplies, please check state mandates.

Lymphedema Stockings for the Arm

Lymphedema stockings for the arm are covered on an unlimited basis as to number of items and dollar amounts covered as required by the Women's Health and Cancer Rights Act (WHCRA) of 1998.

Medical Supplies

Medical Supplies that are used with covered DME are covered when the supply is necessary for the effective use of the item/device (e.g., oxygen tubing or mask, batteries for power wheelchairs and prosthetics, or tubing for a delivery pump).

Mobility Devices

Mobility Devices (manual wheelchair, electric wheelchairs, transfer chair or scooters/Power-Operated Vehicles (POV)) are a Covered Health Care Service when Medically Necessary. Please check the member specific benefit plan document for coverage of Mobility Devices.

- Proof of the home evaluation is not required at the time of prior authorization. The on-site home evaluation can be performed prior to, or at the time of, delivery of a Power Mobility Device. The written report of the home evaluation must be available on request post-delivery.

Oral Appliances

Oral appliances for snoring are excluded. Coverage may be provided for oral appliances (prefabricated or custom fabricated) for sleep apnea (HCPCS E0485 and E0486). Refer to the Medical Policy titled [Obstructive Sleep Apnea Treatment](#).

- A letter of referral or prescription to the dentist for the appliance must be received from the treating physician; and
- A polysomnography must be completed documenting Obstructive Sleep Apnea.

Orthotic Braces

Orthotic braces that stabilize an injured body part and braces to treat curvature of the spine are considered DME (see [Coverage Limitations and Exclusions](#)). Examples of orthotic braces include but are not limited to:

- Thoracic-lumbar-sacral orthotic (TLSO)
- Lumbar-sacral orthotic (LSO)
- Knee orthotics (KO)
- Ankle Foot Orthotic (AFO)
- Necessary adjustments to shoes to accommodate braces

Note: There are specific codes that are defined by HCPCS as orthotics that UnitedHealthcare covers as DME.

Ostomy Supplies

Ostomy Supplies are limited to the following:

- Pouches, face plates and belts
- Irrigation sleeves, bags and ostomy irrigation catheters
- Skin barriers

Benefits are not available for deodorants, filters, lubricants, tape, appliance cleaners, adhesive, adhesive remover, or other items not listed above (please check the member specific benefit plan document for coverage of ostomy supplies).

Pleurx Bottles and Tubing

Pleurx bottles and tubing are covered as DME.

Repair and Replacement

Repair and replacement of DME is covered when the member has a DME benefit and any of the following:

- The repairs, including the replacement of essential accessories, such as hoses, tubes, mouth pieces, etc., for necessary DME are covered when necessary to make the item/device serviceable;
- The physician provides documentation that the condition of the member changes (e.g., impaired function necessitates an upgrade to an electric wheelchair from a manual one);
- Routine wear on the equipment renders it non-functional and the member still requires the equipment.

- Vendors/manufacturers are responsible for repairs, replacements, and maintenance for rented equipment and for purchased equipment covered by warranty.
- Coverage includes DME obtained in a physician's office, DME vendor, or any other provider authorized to provide/dispense DME.
- Frequency and timeframe limits for DME repair or replacement are specified in the member's specific benefit plan documents.

Speech Generating Devices

Speech Generating Devices are covered as DME when they are not explicitly excluded from coverage in the member specific benefit plan document (COC or SPD) and the treating physician determines that the member suffers from severe speech impairment and that the medical condition warrants the use of a device based upon the definitions below. The physician attestation must be consistent with and based upon the recommendation of a qualified speech and language pathologist. The speech and language pathology evaluation must reach all of the following conclusions:

- The member's medical condition is one resulting in a severe expressive speech impairment;
- The member's speaking needs cannot be met using natural communication methods;
- Other forms of treatment have been attempted or considered and ruled out. Examples of a Speech Generating Device are:
 - Dynavox
 - Freedom
 - Say-it![™]

Note: Please check the member specific benefit plan document for coverage of Speech Generating Devices.

Trachea-Esophageal and Voice Aid Prosthetics

Trachea-esophageal prosthetics and voice aid prosthetics are covered as DME.

Ventilators and Respiratory Assist Devices

For adult or pediatric members, UnitedHealthcare uses the Medicare policy for coverage determinations for home ventilators. Home ventilators are:

- Not covered for non-life-threatening conditions.
- Not covered when used as Respiratory Assistance Devices (RAD).

Regardless of the member's age, any type of ventilator would not be eligible for reimbursement for any of the conditions described in the [Medicare RAD criteria](#) even though the ventilator may have the capability of operating in a bi-level PAP (E0470, E0471) mode.

- The conditions that qualify for use of a RAD are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death.
- Claims for ventilators, such as Trilogy mechanical ventilators, (E0465, E0466) used for the treatment of conditions described in the Medicare RAD criteria are not covered. Bi-level PAP devices (E0470, E0471) are considered as Medically Necessary in those clinical scenarios.
- Ventilators must not be billed using codes for CPAP (E0601) or bi-level PAP (E0470, E0471, and E0472). The use of CPAP or bi-level PAP HCPCS codes to bill a ventilator is incorrect coding, even if the ventilator is only being used in CPAP or bi-level mode.

PAP Therapy

Note: For the evaluation of PAP therapy, hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in airflow and with at least a 3% decrease in oxygen saturation from pre-event baseline or the event is associated with an arousal (AASM Scoring Manual, 2017).

Medical Necessity Plans

In the absence of a related policy or coverage indication from above, UnitedHealthcare uses available criteria from the [DME MAC](#).

DME, related supplies, and orthotics are Medically Necessary when:

- Ordered by a physician; and
- The item(s) meets the plans Medically Necessary definition (refer to the member specific benefit plan document); and
- CMS DME MAC criteria are met (see above link); and
- The item is not otherwise excluded from coverage.

Coverage Limitations and Exclusions

- When more than one piece of DME can meet the member's functional needs, benefits are available only for the item that meets the minimum specifications for member needs. Examples include but are not limited to: standard electric wheelchair vs. custom wheelchair; standard bed vs semi-electric bed vs fully electric or flotation system. This limitation is intended to exclude coverage for deluxe or additional components of a DME item which are not necessary to meet the member's minimal specifications to treat an Injury or Sickness.
- When the member rents or purchases a piece of DME that exceeds this guideline, the member will be responsible for any cost difference between the piece he/she rents or purchases and the piece we have determined is the most cost-effective.
- Additional accessories to DME items or devices which are primarily for the comfort or convenience of the member are not covered. Examples include but are not limited to:
 - Air conditioners
 - Humidifiers
 - Air purifiers and filters
 - Remodeling or modification to home or vehicle to accommodate DME or patient condition (e.g., Ramps, stair lifts and stair glides, wheelchair lifts, bathroom modifications, door modifications)
 - Batteries for non-medical equipment (e.g., flashlights, smoke detectors, telephones, watches, weight scales)
- Orthotic braces that straighten or change the shape of a body part are excluded from coverage.
- Upgrade or replacement of DME when the existing equipment is still functional is not covered.
- Replacement of items due to malicious damage, neglect or abuse is not covered.
- Replacement of lost or stolen items is not covered.
- Routine periodic maintenance (e.g., testing, cleaning, regulating and checking of equipment) for which the owner or vendor is generally responsible is not covered.
- DME and supplies that are explicitly excluded in the member specific benefit plan document are not covered.
- Elastic splints, sleeves or bandages are not covered, unless part of a Covered Health Care Service (e.g., sleeve used in conjunction with a lymphedema pump or bandages used with complex decongestive therapy).
- Devices used specifically as safety items or to affect performance in sports-related activities are not covered.
- Diagnostic or monitoring equipment purchased for home use unless otherwise described as a Covered Health Care Service (e.g., blood pressure monitor, oximeters).
- The following items are excluded even if prescribed by a physician. Please refer to the member specific benefit plan document.
 - Blood pressure cuff/monitor
 - Enuresis alarm
 - Non-wearable external defibrillator
 - Trusses or girdle
 - Ultrasonic nebulizers
- Devices and computers to assist in communication and speech are not covered. However, see [Indications for Coverage](#) for information on Speech Generating Devices.
- Oral appliances for snoring are not covered. See [Indications for Coverage](#) for oral appliances for sleep apnea.
- Personal Care, Comfort and Convenience items and supplies are not covered. Please check the member specific benefit plan document for the list of excluded items.
- Dental braces are also excluded from coverage. Please check the member specific benefit plan document and State Mandates.
- Items and supplies that do not meet the definition of a Covered Health Care Service are not covered.
- Ostomy Supplies are not covered unless specifically stated as covered. Please check the member specific benefit plan document. See [Indications for Coverage](#).
- Medical Supplies (except those described above under [Indications for Coverage](#)) are excluded. This includes, but is not limited to bandages, gauze, dressings, cotton balls and alcohol wipes.
- Urinary catheters are excluded unless specifically stated as covered. Please check the member specific benefit plan document.
- Cranial molding helmets and cranial banding are excluded from coverage except when used to avoid the need for surgery and/or to facilitate a successful surgical outcome.
- Powered and non-powered exoskeleton devices. Prescribed or non-prescribed publicly available devices, software applications and/or monitors that can be used for non-medical purposes (e.g., smart phone applications, software applications).

For ASO Plans with SPD Language other than Fully-Insured Generic COC Language

Please refer to the member's plan specific SPD for coverage.

DEFINITIONS

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

Covered Health Care Service(s): Health Care Services, including supplies or Pharmaceutical Products, which we determine to be all of the following:

- Provided for the purpose of preventing, evaluating, diagnosing or treating a Sickness, Injury, Mental Illness, substance-related and addictive disorders, condition, disease or its symptoms.
- Medically Necessary
- Described as a Covered Health Care Service in the *COC* under *Section 1: Covered Health Care Services* and in the *Schedule of Benefits*
- Not excluded in the *COC* under *Section 2: Exclusions and Limitations*

Durable Medical Equipment: Medical Equipment that is all of the following:

- Ordered or provided by a Physician for outpatient use primarily in a home setting
- Used for medical purposes
- Not consumable or disposable except as needed for the effective use of covered DME
- Not of use to a person in the absence of a disease or disability
- Serves a medical purpose for the treatment of a Sickness or injury
- Primarily used within the home

Medical Supplies: Expendable items required for care related to a medical illness or dysfunction.

Medically Necessary: Health Care Services that are all of the following as determined by us or our designee.

- In accordance with *Generally Accepted Standards of Medical Practice*.
- Clinically appropriate, in terms of type, frequency, extent, service site and duration, and considered effective for your Sickness, Injury, Mental Illness, substance-related and addictive disorders, disease or its symptoms.
- Not mainly for your convenience or that of your doctor or other health care provider.
- Not more costly than an alternative drug, service(s), service site or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms.

Mobility Device: A manual wheelchair, electric wheelchair, transfer chair or scooter.

Obstructive Sleep Apnea: The American Academy of Sleep Medicine (AASM) defines Obstructive Sleep Apnea as a sleep related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe.

OSA severity is defined as:

- Mild for AHI or RDI ≥ 5 and < 15
- Moderate for AHI or RDI ≥ 15 and ≤ 30
- Severe for AHI or RDI > 30 /hr

Speech Generating Device: Speech Generating Devices are characterized by the following:

- Are of use only by an individual who has severe speech impairment.
- May have digitized speech output, using pre-recorded messages, less than or equal to 8 minutes recording time
- May have digitized speech output, using pre-recorded messages, greater than 8 minutes recording time.
- May have synthesized speech output, which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques.
- May be software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a Speech Generating Device.
- May have synthesized speech output, which permits multiple methods of message formulation and multiple methods of device access.

Speech Generating Devices are not:

- Devices that are capable of running software for purposes other than for speech generation, e.g., devices that can also run a word processing package, an accounting program, or perform other non-medical function
- Laptop computers, desktop computers, or PDAs which may be programmed to perform the same function as a Speech Generating Device
- Useful to someone without severe speech impairment

APPLICABLE CODES

UnitedHealthcare has adopted the requirements and intent of the National Correct Coding Initiative. The Centers for Medicare & Medicaid Services (CMS) has contracted with Noridian to manage Pricing, Data and Coding (PDAC) for

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). This notice is to confirm UnitedHealthcare has established the PDAC as its definitive source for correct coding and coding clarification.

REFERENCES

Centers for Medicare and Medicaid Services (CMS), Correct Coding and Coverage of Ventilators” dated January 1, 2016; available at https://www.dmepdac.com/resources/articles/2015/12_15_15.html. Accessed October 3, 2018.

Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Pub. 100-2, Chapter 14, §10, Coverage of Medical Devices.

Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Pub. 100-2, Chapter 15, §110 Durable Medical Equipment – General.

Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Pub. 100-2, Chapter 15, §110.4 Repairs, Maintenance, Replacement, and Delivery.

Centers for Medicare and Medicaid Services (CMS). Medicare National Coverage Determinations Manual (Pub. 100-3), Chapter 1, Part 4 (Sections 200 – 310.1), § 280.

Medical and Surgical Supplies Coverage Determinations Medicare Coverage Issues Manual, Pub. 6, §60-9.

GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	<ul style="list-style-type: none"> • Updated coverage rationale: <ul style="list-style-type: none"> Indications for Coverage ○ Replaced language indicating: <ul style="list-style-type: none"> ▪ “Breast pumps may be covered <i>as DME</i>” with “breast pumps may be covered <i>under the preventive care services benefit</i>” ▪ “Mobility Devices (manual wheelchair, electric wheelchairs, transfer chair or scooters) are a Covered Health Care Service” with “Mobility Devices (manual wheelchair, electric wheelchairs, transfer chair or scooters/<i>power-operated vehicles</i>) are a Covered Health Care Service <i>when Medically Necessary</i>” ○ Added language to clarify: <ul style="list-style-type: none"> ▪ Cranial <i>molding</i> helmets (cranial remolding orthosis, billed with S1040) used to facilitate a successful post-surgical outcome are covered as DME and are not subject to the orthotic device exclusion ▪ For Mobility Devices, proof of the home evaluation is not required at the time of prior authorization <ul style="list-style-type: none"> - The on-site home evaluation can be performed prior to, or at the time of, delivery of a Power Mobility Device - The written report of the home evaluation must be available on request post-delivery Coverage Limitations and Exclusions ○ Replaced language indicating “cranial helmets <i>used for other indications other than those in the Indications for Coverage [of the policy]</i> are excluded from coverage <i>under the orthotics exclusion</i>” with “cranial <i>molding</i> helmets and <i>cranial banding</i> are excluded from coverage <i>except when used to avoid the need for surgery and/or to facilitate a successful surgical outcome</i>” ○ Added language to clarify powered and non-powered exoskeleton devices are excluded from coverage • Updated definition of: <ul style="list-style-type: none"> ○ Covered Health Care Service(s) ○ Medically Necessary • Archived previous policy version CDG.009.11